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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/628,568	07/31/00	PRESTA L	A-63470-7/DA

HM12/0904
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EXAMINER	
SAUNDERS, D	
ART UNIT	**PAPER NUMBER**
1644	6

DATE MAILED: 09/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
628,568	PRESTA et al
Examiner	**Group Art Unit**
SAUNDERS	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 7/3/00.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

The preliminary amendment of 7/31/00 (Paper 4) has been entered. Claim 1 is pending and under examination.

The disclosure is objected to because of the following informalities: at page 1, the status of Parent application 08/422,112 must be indicated.

At page 4, line 13, reference should be made to --FIGS 2A and 2B-- rather than "FIG 2", since FIG 2 appears on 2 sheets.

Appropriate correction is required.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The disclosure has not given an adequate description of the nucle acid encoding a "variant which comprises a salvage receptor binding epitope of an Fc region of an IgG".

Except for the representative epitopes shown in Figure 2 (referenced at page 6, lines 29-30), or as defined by SEQ ID NOS: (page 14, lines 10-18), applicant has not adequately described the genus of recited epitopes in structural terms. Presumably, the genus is large and has many structural variants obtainable form different antibody isotopes, from different animal species (as well as from different allotypes within an animal species), and by engineered modifications of the above variants. The limited exemplification given in Figure 2 and by the taught SEQ ID NOS, however, does not provide an adequate representation of the genus.

Note that mere statements as to what the source is (an Fc domain), as to how to obtain the epitope (e.g. identifying methods, as broadly taught at page 3, lines 15+), and as to what the function is do not provide a description of the desired epitope as a product per se.

Applicant is referred to Reagents of the University of California v. Eli Lilly 43 USPQ2d 1398 and to the Revised Interim Description Guidelines, 1242 OG, January 30, 2001.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Pastan et al (WO 94/04689) or Batra et al (Molecular Immunology 1993).

Pastan et al teach various constructs of a CD4-PE40 fusion protein which contain inserts of CH2, CH3, CH1-CH2, or CH2-CH3. Fusion proteins having any of these inserts show an improved circulation half life. See Table 3 at page 14, for example. Pastan et al disclose nucleic acids encoding these constructs.

Anticipation is properly stated because the polypeptide of interest (CD4-PE40) "does not contain a Fc region of an Ig G". Further, the introduction of these sequences to the CD4-PE40 fusion protein is taught as altering renal clearance (page 17, lines -18). Clearly, from applicant's own disclosure, the constructs of Pastan et al that have insets containing a CH2 domain would contain the epitope of applicant taken form two loops of the CH2 domain (instant specification

page 13, lines 26-35 and page 17, lines 12-19). It is noted applicant's claims place no limit upon the size of the "salvage receptor binding epitope"; thus the claims encompass nucleic acid encoding insertion of a whole CH2 domain, as shown by Pastan et al.

Batra et al teach the same modifications of the CD4-PE40 fusion protein as Pastan et al and are thus also cited.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,121,022. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and copending claims are each drawn to the same essential invention of a nucleic acid encoding a polypeptide variant having a salvage receptor binding epitope as the essential feature defining the variant.

While the issued claims more narrowly define this epitope and the manner by which the polypeptide variant is to be modified, these issued claims are clearly drawn to subject matter

encompassed by the instant claim. Therefore a terminal disclaimer is required in order to assure that common ownership of the issued patent and any patent issuing from the instant application will be maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders Ph.D. whose telephone number is (703) 308-3976. The examiner can normally be reached on M-F from 8:15 am to 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Saunders:mv

August 13, 2001

David A. Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644